DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
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June 30, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas J. Hillman
President
The Fresh Fish Co., Inc.
8501 Page Blvd.
St. Louis, Missouri 63114

Re: STL-99-05

Dear Mr. Hillman:

An inspection of your firm on April 14-16, 1999, by a Food and Drug Administration Investigator from this office revealed histamine and non-histamine prone fishery species, and molluscan shellfish are processed at, and distributed from, your facility under serious deviations from Title 21, Code of Federal Regulations (21 CFR), Part 123. These deviations cause these products to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act).

As we explained in a previous letter to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed your processing of molluscan shellfish, histamine and non-histamine prone species deviates from the regulations contained 21 CFR Part 123 summarized as follows:

1. Failure to take corrective action(s), or document the reason(s) for a lack thereof, when a critical limit is exceeded, as required by 21 CFR 123.7(a). For example, the cooler storage temperature exceeded the HACCP plan's critical limit temperature of 40 F on March 27-29, 1999. We note from the monitoring records that the cooler temperatures to reached [redacted] during the three consecutive days.

2. Failure to develop and implement a written HACCP plan, when one is needed, for fresh (refrigerated) and frozen molluscan shellfish; vacuum packaged smoked fish (salmon and trout); pickled fish (herring); and acidified seafood (anchovy paste), as required by 21 CFR 123.6(b).

3. We observed inconsistencies in your HACCP system records. For example, the form used for recording fishery product temperatures in cooler storage states that fresh product must not meet or exceed 50 F. This contradicts the critical limit in your HACCP plans for both histamine and non-histamine prone fish, which state that the cooler and product critical limit is 40 F.

4. The HACCP plan for the processing of vacuum packaged tuna is inadequate because it does not identify Clostridium botulinum as a potential hazard at the packaging step and beyond.

Other observations about your seafood processing systems were provided to you in detail by the FDA investigator noted in the FDA-483:

1. The HACCP Plan for histamine prone fish states that ice and gel packs will be checked. However, there is no documentation to show that it has been followed.

2. There are no calibration records to show that the mercury in glass thermometer in the cooler has been properly calibrated. The existing records are inadequate in that they do not show the actual temperature reading.

3. Failure to sign and date the HACCP Plan by the most responsible individual as required by 21 CFR 123.6(d).

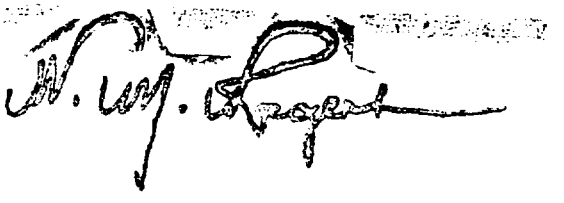
This letter is not intended to be all-inclusive list of deficiencies at your facility. At the conclusion of the inspection you were issued a Form FDA-483, Inspectional Observations, which is a list of the investigator's observations of deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expected to complete your correction.

Your reply should be sent to Andrew H. Paeng, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
Director
Kansas City District